UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

[redacted]

JUN 07 2019

Re: LVE L-19-0033

Dear [redacted]

This letter responds to the above-referenced Low Volume Exemption (LVE) notice, received by the Environmental Protection Agency (EPA) on November 14, 2018. The notice review period expired on June 7, 2019. After that date, you became free to manufacture or import this substance under the terms of the Low Volume Exemption at 40 CFR 723.50.

EPA has evaluated the conditions of use of your LVE notice considering information provided in the original submission as well as the additional information submitted to the Agency on April 11, 2019, in response to hazard concerns identified in EPA's initial assessment based on analogues. Upon consideration of the additional information submitted, EPA has reconsidered its assessment. First, EPA reassessed the appropriateness of the analogue used to identify potential lung effects. EPA considered the information provided and agrees that the analogue used for the initial hazard identification likely contains chemistries that differ (*i.e.*, are more reactive) from the LVE substance. This structure-activity analysis is further supported by the study by [redacted]. These lines of evidence have led EPA to conclude waterproofing effects in the lung are not expected; however, uncertainty associated with this conclusion remains. EPA also revisited the plausibility of the LVE substance degrading to [redacted] more specifically within the context of each anticipated exposure route. In brief, EPA does not expect exposure to [redacted] would result from dermal exposures to the LVE substance due to the lack of absorption predicted via this route of exposure nor from inhalation exposure to the LVE substance due to a combination of the lack of absorption of the LVE substance and lack of pH environment to facilitate hydrolysis of [redacted] from the LVE in the environment of the lung. EPA continues to include assessment of exposures to [redacted] under scenarios wherein the LVE is expected to degrade into [redacted], *i.e.*, via oral exposure and via inhalation exposure following disposal or environmental processes.

In summary, after considering additional information submitted to the Agency, EPA has revised its human health risk assessment and, based on a weight-of-evidence approach, concludes that waterproofing effects on the lung are not expected based on the chemistry of the LVE. In addition, EPA has assessed risks from exposure to [redacted] under plausible scenarios and did not identify risks associated with these exposures. EPA notes that, while the information available did allow EPA to conduct a reasoned evaluation, there is generally uncertainty associated with potential 'waterproofing' effects on the lung; these uncertainties were weighed in making the determination for this LVE. EPA continues to be concerned that the LVE substance could degrade to persistent, bioaccumulative, and toxic chemicals, including [redacted]

EPA acknowledges the commitment made in the LVE application submitted to EPA by [redacted] and its parent company, [redacted], to reduce the presence of PFAS in [redacted] through the development of high-performance, non-fluorinated alternatives. EPA acknowledges that [redacted] has moved from C8 chemistry to the [redacted] found in [redacted] today, that [redacted] now offers non-fluorinated products in certain [redacted] categories, that [redacted] has plans to reduce and eliminate PFAS from [redacted] in the coming years, and that [redacted] is also a supporting private-sector member of the [redacted] initiative supporting the development of PFAS-free consumer products, including [redacted].

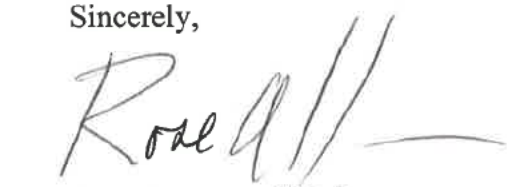
Based on the above information and the following requirements, EPA has approved this LVE for a three-year period due to the exposure limitations provided in your notice, including limiting import to no more than [redacted] kg/yr, communicating to users via the Safety Data Sheet (SDS) and labels on your product that [redacted] must occur in a well-ventilated area, and your agreement to limit import under this exemption to a three-year period. The three-year period will end on June 7, 2022. The Agency anticipates that during that period, [redacted] will eliminate all fluorocarbon substances in [redacted] in its products. Your commitment to this limit on the duration of manufacture is legally binding and enforceable as a human exposure and environmental release control under 40 CFR 723.50(j)(1).

If you wish to continue import of this material after June 7, 2022, you must submit a new LVE or PMN for EPA's review early enough that the review period for that new LVE or PMN will expire before June 7, 2022. Please include a cover letter if you submit a new LVE or PMN for this substance which references this LVE (L-19-0033) and its expiration date.

40 CFR 723.50(j) requires that the LVE substance "must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice." Further, 40 CFR 723.50(k) requires your company to notify processors and industrial users of the exposure controls and use limitations specified in the exemption notice. If you learn that a customer is processing or using the LVE substance in violation of such restrictions, you must immediately cease distribution of the LVE substance to that customer or comply with the procedures specified in subsection 723.50(k)(3).

Thank you for your cooperation. If you have any questions or comments, please contact Alie Muneer, the Program Manager for this LVE, at (202) 564-6369.

Sincerely,



for Greg Schweer, Chief
New Chemicals Management Branch
Chemical Control Division (7405 M)